

HFA 305

Approval letter dated: JUN 13 2002

FREEDOM OF INFORMATION SUMMARY

**SUPPLEMENTAL ABBREVIATED NEW ANIMAL
DRUG APPLICATION**

ANADA 200-154

Pennox 200 Injection

“addition for use in lactating dairy cattle”

Sponsored by:

Pennfield Oil Company
Omaha, Nebraska 68144

ANADA 200-154

FOIS.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

ANADA Number: 200-154

Sponsor: Pennfield Oil Company
14040 Industrial Road
Omaha, Nebraska 68144

Drug Labeler Code: 053389

Generic Name: Oxytetracycline Hydrochloride, USP

Pioneer Product: Pfizer, Inc., Liquamycin[®] LA-200
NADA 113-232

Trade Name: Pennox 200 Injection

Dosage Form: Injectable

Effect of Supplement: The supplement provides for use in lactating dairy cattle.

Route of Administration: Intramuscular in swine, Intramuscular,
Intravenous, and Subcutaneous in cattle

Indications for Use:**Cattle: Beef and dairy, calves including pre-ruminating veal calves.**

For the treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp., *Haemophilus* spp.; infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*; foot rot and diphtheria caused by *Fusobacterium necrophorum*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresii*; leptospirosis caused by *Leptospira pomona*; and wound infections and acute metritis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline.

Swine:

For the treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*; pneumonia caused by *Pasteurella multocida*; and leptospirosis caused by *Leptospira pomona*. In sows, it is indicated as an aid in the control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli*.

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act, (53 FR 50460, December 15, 1988, First GADPTRA Policy Letter) an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an ANADA. An ANADA relies on the target animal safety, drug effectiveness, and human food safety data in the pioneer's new animal drug application. The ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer. ANADAs for drug products for food-producing animals will generally be required to include bioequivalence and tissue residue studies. A tissue residue study will generally be required to accompany clinical end-point and pharmacologic end-point bioequivalence studies, and blood level bioequivalence studies that can not quantify the concentration of the drug in blood throughout the established withdrawal period.

For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 10, 2000).

Based upon the formulation characteristics of the generic product, PENNOX 200 Injection was granted a waiver from conducting an *in vivo* bioequivalence study. The abbreviated new animal drug application was approved on May 8, 1996. The generic and pioneer products contain the same active and inactive ingredients and are parenteral solutions.

3. HUMAN FOOD SAFETY

The previous withdrawal periods and tolerances remain unchanged. Therefore, no human food safety information is required.

Withdrawal periods: Cattle & Swine 28 days

REGULATORY METHOD:

The regulatory method for determination of oxytetracycline in tissues is a microbiological assay procedure using *Bacillus cereus* var. *mycoides* (ATCC 11778) suspension and is found in the FDA publication "Antibiotic Residues in Milk, Dairy Products, and Animal Tissues: Methods, Reports, and Protocols" revised October 1968, reprinted December 1974. (Available from the FDA, Center for Veterinary Medicine, 7500 Standish Place, Rockville, Maryland 20855.)

4. AGENCY CONCLUSIONS:

This Supplemental Abbreviated New Animal Drug Application (ANADA) filed under section 512(b) of the Federal, Food, Drug and Cosmetic Act satisfies the requirements of section 512(n) of the Act and demonstrates that Pennox 200 Injection is safe and effective for its labeled indications, when used under its proposed conditions of use.

5. LABELING:

Attachments:

Pioneer Labeling:

Package Insert

100, 250, & 500 mL bottles

Cartons

Generic Labeling:

Package Insert

500 mL bottles

Copies of applicable labels may be obtained by writing to the:

Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

Or requests may be sent via fax to: (301) 443-1726. If there are problems sending a fax, call (301) 827-6567.

Liquamycin® LA-200®

(oxytetracycline injection)

Antibiotic

Each mL contains 200 mg of oxytetracycline base as amphoteric oxytetracycline.

For use in beef cattle; dairy cattle; calves, including preruminating (veal) calves; and swine

For animal use only

Read Entire Package Insert Carefully Before Using This Product

Liquamycin LA-200 (oxytetracycline injection) is a sterile, ready-to-use solution for the administration of the broad-spectrum antibiotic oxytetracycline (Terramycin®) by injection. Terramycin, discovered by Pfizer scientists, is an antimicrobial agent that is effective in the treatment of a wide range of diseases caused by susceptible gram-positive and gram-negative bacteria.

Liquamycin LA-200 administered to cattle or swine for the treatment of bacterial pneumonia at an intramuscular dosage of 9 mg of oxytetracycline per lb of body weight has been demonstrated in clinical trials to be as effective as 2 or 3 repeated, daily treatments of Terramycin Injectable at 3–5 mg/lb of body weight.

Liquamycin LA-200 does not require refrigeration; however, it is recommended that it be stored at room temperature, 15°–30°C (59°–86°F). The antibiotic activity of oxytetracycline is not appreciably diminished in the presence of body fluids, serum, or exudates.

CAUTION: When administered to cattle, muscle discoloration may necessitate trimming of the injection site(s) and surrounding tissues during the dressing procedure.

WARNINGS: Discontinue treatment at least 28 days prior to slaughter of cattle and swine. Milk taken from animals during treatment and for 96 hours after the last treatment must not be used for food.

PRECAUTIONS: Exceeding the highest recommended dosage level of drug per lb of body weight per day, administering more than the recommended number of treatments, and/or exceeding 10 mL intramuscularly or subcutaneously per injection site in adult beef and dairy cattle, and 5 mL intramuscularly per injection site in adult swine, may result in antibiotic residues beyond the withdrawal period.

Reactions of an allergic or anaphylactic nature, sometimes fatal, have been known to occur in hypersensitive animals following the injection of oxytetracycline. Such adverse reactions can be characterized by signs such as restlessness, erection of hair, muscle trembling; swelling of eyelids, ears, muzzle, anus, and vulva (or scrotum and sheath in males); labored breathing, defecation and urination, glassy-eyed appearance, eruption of skin plaques, frothing from the mouth, and prostration. Pregnant animals that recover may subsequently abort. At the first sign of any adverse reaction, discontinue use of this product and administer epinephrine at the recommended dosage levels. Call a veterinarian immediately.

Shock may be observed following intravenous administration, especially where highly concentrated materials are involved. To minimize this occurrence, it is recommended that Liquamycin LA-200 be administered *slowly* by this route.

Shortly after injection, treated animals may have transient hemoglobinuria resulting in darkened urine.

As with all antibiotic preparations, use of this drug may result in overgrowth of non-susceptible organisms, including fungi. A lack of response by the treated animal, or the development of new signs, may suggest that an overgrowth of nonsusceptible organisms has occurred. If any of these conditions occur, consult your veterinarian.

Since bacteriostatic drugs may interfere with the bactericidal action of penicillin, it is advisable to avoid giving Liquamycin LA-200 in conjunction with penicillin.

STORAGE: Store at room temperature 15°–30°C (59°–86°F). Keep from freezing.

CARE OF SICK ANIMALS: The use of antibiotics in the management of diseases is based on an accurate diagnosis and an adequate course of treatment. When properly used in the treatment of diseases caused by oxytetracycline-susceptible organisms, most animals that have been treated with Liquamycin LA-200 show a noticeable improvement within 24–48 hours. It is recommended that the diagnosis and treatment of animal diseases be carried out by a veterinarian. Since many diseases look alike but require different types of treatment, the use of professional veterinary and laboratory services can reduce treatment time, costs, and needless losses. Good housing, sanitation, and nutrition are important in the maintenance of healthy animals, and are essential in the treatment of diseased animals.

INDICATIONS: Liquamycin LA-200 is intended for use in the treatment of the following diseases in beef cattle; dairy cattle; calves, including preruminating (veal) calves; and swine when due to oxytetracycline-susceptible organisms:

Cattle: Liquamycin LA-200 is indicated in the treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Hemophilus* spp.; infectious bovine keratoconjunctivitis (pink eye) caused by *Moraxella bovis*; foot rot and diarr-

Shortly after injection, treated animals may have transient hemoglobinuria resulting in darkened urine.

As with all antibiotic preparations, use of this drug may result in overgrowth of non-susceptible organisms, including fungi. A lack of response by the treated animal, or the development of new signs, may suggest that an overgrowth of nonsusceptible organisms has occurred. If any of these conditions occur, consult your veterinarian.

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INDICATIONS: Liquamycin LA-200 is intended for use in the treatment of the following diseases in beef cattle; dairy cattle; calves, including preruminating (veal) calves; and swine when due to oxytetracycline-susceptible organisms:

Cattle: Liquamycin LA-200 is indicated in the treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Hemophilus* spp.; infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*; foot rot and diphtheria caused by *Fusobacterium necrophorum*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresii*; leptospirosis caused by *Leptospira pomona*; and wound infections and acute metritis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline.

Swine: Liquamycin LA-200 is indicated in the treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*; pneumonia caused by *Pasteurella multocida*; and leptospirosis caused by *Leptospira pomona*.

In sows, Liquamycin LA-200 is indicated as an aid in the control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli*.

DOSAGE:

Cattle: Liquamycin LA-200 is to be administered by intramuscular, subcutaneous, or intravenous injection to beef cattle; dairy cattle; and calves, including preruminating (veal) calves.

A single dosage of 9 mg of Liquamycin LA-200 per lb of body weight administered intramuscularly or subcutaneously is recommended in the treatment of the following conditions: 1) bacterial pneumonia caused by *Pasteurella* spp. (shipping fever) in calves and yearlings, where retreatment is impractical due to husbandry conditions, such as cattle on range, or where their repeated restraint is inadvisable; 2) infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*.

Liquamycin LA-200 can also be administered by intravenous, subcutaneous, or intramuscular injection at a level of 3–5 mg of oxytetracycline per lb of body weight per day. In the treatment of severe foot rot and advanced cases of other indicated diseases, a dosage level of 5 mg/lb of body weight per day is recommended. Treatment should be continued 24–48 hours following remission of disease signs; however, not to exceed a total of 4 consecutive days. Consult your veterinarian if improvement is not noted within 24–48 hours of the beginning of treatment.

Swine: A single dosage of 9 mg of Liquamycin LA-200 per lb of body weight administered intramuscularly is recommended in the treatment of bacterial pneumonia caused by *Pasteurella multocida* in swine, where retreatment is impractical due to husbandry conditions or where repeated restraint is inadvisable.

Liquamycin LA-200 can also be administered by intramuscular injection at a level of 3–5 mg of oxytetracycline per lb of body weight per day. Treatment should be continued 24–48 hours following remission of disease signs; however, not to exceed a total of 4 consecutive days. Consult your veterinarian if improvement is not noted within 24–48 hours of the beginning of treatment.

For sows, administer once intramuscularly 3 mg of oxytetracycline per lb of body weight approximately 8 hours before farrowing or immediately after completion of farrowing.

For swine weighing 25 lb of body weight and under, Liquamycin LA-200 should be administered undiluted for treatment at 9 mg/lb but should be administered diluted for treatment at 3 or 5 mg/lb.

Body Weight	9 mg/lb Dosage		3 or 5 mg/lb Dosage		
	Volume of Undiluted Liquamycin LA-200		Volume of Diluted Liquamycin LA-200		
	9 mg/lb		3 mg/lb	Dilution*	5 mg/lb
5 lb	0.2 mL		0.6 mL	1:7	1.0 mL
10 lb	0.5 mL		0.9 mL	1:5	1.5 mL

DIRECTIONS FOR USE: Liquamycin LA-200 is intended for use in the treatment of disease due to oxytetracycline-susceptible organisms in beef cattle; dairy cattle; calves, including preruminating (veal) calves; and swine. A thoroughly cleaned, sterile needle and syringe should be used for each injection (needles and syringes may be sterilized by boiling in water for 15 minutes). In cold weather, Liquamycin LA-200 should be warmed to room temperature before administration to animals. Before withdrawing the solution from the bottle, disinfect the rubber cap on the bottle with suitable disinfectant, such as 70% alcohol. The injection site should be similarly cleaned with the disinfectant. Needles of 16-18 gauge and 1-1½ inches long are adequate for intramuscular and subcutaneous injections. Needles 2-3 inches are recommended for intravenous use.

Intramuscular Administration:

Intramuscular injections should be made by directing the needle of suitable gauge and length into the fleshy part of a thick muscle such as in the rump, hip, or thigh regions; avoid blood vessels and major nerves. Before injecting the solution, pull back gently on the plunger. If blood appears in the syringe, a blood vessel has been entered; withdraw the needle and select a different site. No more than 10 mL should be injected intramuscularly at any one site in adult beef and dairy cattle, and not more than 5 mL per site in adult swine; rotate injection sites for each succeeding treatment. The volume administered per injection site should be reduced according to age and body size so that 1-2 mL per site is injected in small calves.

Subcutaneous Administration:

Subcutaneous injections in beef cattle, dairy cattle, and calves, including preruminating (veal) calves, should be made by directing the needle of suitable gauge and length through the loose folds of the neck skin in front of the shoulder. Care should be taken to ensure that the tip of the needle has penetrated the skin but is not lodged in muscle. Before injecting the solution, pull back gently on the plunger. If blood appears in the syringe, a blood vessel has been entered; withdraw the needle and select a different site. The solution should be injected slowly into the area between the skin and muscles. No more than 10 mL should be injected subcutaneously at any one site in adult beef and dairy cattle; rotate injection sites for each succeeding treatment. The volume administered per injection site should be reduced according to age and body size so that 1-2 mL per site is injected in small calves.

Intravenous Administration:

Liquamycin LA-200 may be administered intravenously to beef and dairy cattle. As with all highly concentrated materials, Liquamycin LA-200 should be administered *slowly* by the intravenous route.

Preparation of the Animal for Injection:

1. Approximate location of vein. The jugular vein runs in the jugular groove on each side of the neck from the angle of the jaw to just above the brisket and slightly above and to the side of the windpipe (see Fig. I).
2. Restraint. A stanchion or chute is ideal for restraining the animal. With a halter, rope, or cattle leader (nose tongs), pull the animal's head around the side of the stanchion, cattle chute, or post in such a manner to form a bow in the neck (see Fig. II), then snub the head securely to prevent movement. By forming the bow in the neck, the outside curvature of the bow tends to expose the jugular vein and make it easily accessible. **Caution:** Avoid restraining the animal with a tight rope or halter around the throat or upper neck which might impede blood flow. Animals that are down present no problem so far as restraint is concerned.
3. Clip hair in area where injection is to be made (over the vein in the upper third of the neck). Clean and disinfect the skin with alcohol or other suitable antiseptic.

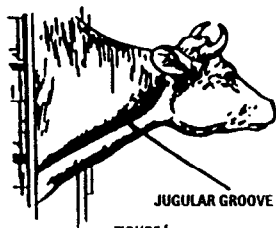


FIGURE I



FIGURE II

Entering the Vein and Making the Injection:

1. Raise the vein. This is accomplished by tying the choke rope tightly around the neck close to the shoulder. The rope should be tied in such a way that it will not come loose and so that it can be untied quickly by pulling the loose end (see Fig. II). In thick-necked animals, a block of wood placed in the jugular groove between the rope and the hide will help considerably in applying the desired pressure at the right point. The vein is a soft flexible tube through which blood flows back to the heart. Under ordinary conditions it cannot be seen or felt with the fingers. When the flow of blood is blocked at the base of the neck by the choke rope, the vein becomes enlarged and rigid because of the back pressure. If the choke rope is sufficiently tight, the vein stands out and can be easily seen and felt in thin-necked animals. As a further check in

throat or upper neck which might impose stress—no problem so far as restraint is concerned.

3. Clip hair in area where injection is to be made (over the vein in the upper third of the neck). Clean and disinfect the skin with alcohol or other suitable antiseptic.

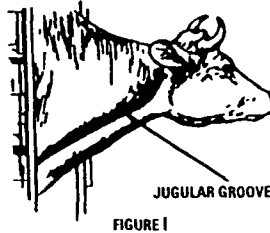


FIGURE I

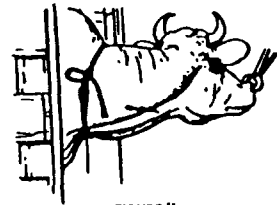


FIGURE II

Entering the Vein and Making the Injection:

1. Raise the vein. This is accomplished by tying the choke rope tightly around the neck close to the shoulder. The rope should be tied in such a way that it will not come loose and so that it can be untied quickly by pulling the loose end (see Fig. II). In thick-necked animals, a block of wood placed in the jugular groove between the rope and the hide will help considerably in applying the desired pressure at the right point. The vein is a soft flexible tube through which blood flows back to the heart. Under ordinary conditions it cannot be seen or felt with the fingers. When the flow of blood is blocked at the base of the neck by the choke rope, the vein becomes enlarged and rigid because of the back pressure. If the choke rope is sufficiently tight, the vein stands out and can be easily seen and felt in thin-necked animals. As a further check in identifying the vein, tap it with the fingers in front of the choke rope. Pulsations that can be seen or felt with the fingers in front of the point being tapped will confirm the fact that the vein is properly distended. It is impossible to put the needle into the vein unless it is distended. Experienced operators are able to raise the vein simply by hand pressure, but the use of a choke rope is more certain.

2. Inserting the needle. This involves 3 distinct steps. First, insert the needle through the hide. Second, insert the needle into the vein. This may require 2 or 3 attempts before the vein is entered. The vein has a tendency to roll away from the point of the needle, especially if the needle is not sharp. The vein can be steadied with the thumb and finger of one hand. With the other hand, the needle point is placed directly over the vein, slanting it so that its direction is along the length of the vein, either toward the head or toward the heart. Properly positioned this way, a quick thrust of the needle will be followed by a spurt of blood through the needle, which indicates that the vein has been entered. Third, once in the vein, the needle should be inserted along the length of the vein all the way to the hub, exercising caution to see that the needle does not penetrate the opposite side of the vein. Continuous steady flow of blood through the needle indicates that the needle is still in the vein. If blood does not flow continuously, the needle is out of the vein (or clogged) and another attempt must be made. If difficulty is encountered, it may be advisable to use the vein on the other side of the neck.

3. While the needle is being placed in proper position in the vein, an assistant should get the medication ready so that the injection can be started without delay after the vein has been entered.

4. Making the injection. With the needle in position as indicated by continuous flow of blood, release the choke rope by a quick pull on the free end. This is essential—the medication cannot flow into the vein while it is blocked. Immediately connect the syringe containing Liquamycin LA-200 to the needle and slowly depress the plunger. If there is resistance to depression of the plunger, this indicates that the needle has slipped out of the vein (or is clogged) and the procedure will have to be repeated. Watch for any swelling under the skin near the needle, which would indicate that the medication is not going into the vein. Should this occur, it is best to try the vein on the opposite side of the neck.

5. Removing the needle. When injection is complete, remove needle with straight pull. Then apply pressure over area of injection momentarily to control any bleeding through needle puncture, using cotton soaked in alcohol or other suitable antiseptic.

Restricted Drug (California)—

Use Only as Directed

Not For Human Use

NADA #113-232, Approved by FDA

TAKE TIME



OBSERVE LABEL
DIRECTIONS



Distributed by:

Animal Health

Exton, PA 19341, USA
Div. of Pfizer Inc
NY, NY 10017

79-4984-00-1
June 1998
Printed in USA

113-232

3-21-01



113-23

3/11/1

PULL SLOWLY TO OPEN



Liquamycin LA-200 (oxytetracycline injection) is a sterile, preincubated solution of the broad-spectrum antibiotic, oxytetracycline. Each mL contains 200 mg of oxytetracycline base as amphoteric oxytetracycline, and as a wet base, 40.0% 2-methyl-2,6-pyridinediol, 1.0% potassium acetate, 0.2% sodium formaldehyde sulfoxylate (as a preservative), monobasic sodium phosphate, hydrochloric acid as required to adjust pH.

CAUTION: When administered to cattle, muscle discoloration may necessitate trimming of the carcass and/or discarding of the carcass during the dressing procedure.

Warnings: Discontinue treatment at least 28 days prior to slaughter of cattle and swine. Milk taken from animals during treatment and for 48 hours after the last treatment must not be used for food.

Precautions: Exceeding the highest recommended level of drug per lb of body weight per day, administering more than the recommended number of treatments, and/or exceeding 10 mL intramuscularly or subcutaneously per injection site in adult beef and dairy cattle, and 5 mL intramuscularly per injection site in adult swine, may result in antibiotic residues beyond the withdrawal period.

Dosage: Cattle: A single dosage of 5 mg of oxytetracycline per lb of body weight (4.5 mL/100 lb) administered intramuscularly or subcutaneously is recommended in the treatment of the following conditions: 1) bacterial pneumonia caused by *Pasteurella* spp. (shipping fever) in calves and yearlings, where retreatment is impractical due to husbandry conditions, such as cattle on range, or where repeated retreatment is inadvisable; 2) infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*; Swine: A single dose of 5 mg of oxytetracycline per lb of body weight (4.5 mL/100 lb) administered intramuscularly is recommended in the treatment of bacterial pneumonia caused by *Pasteurella multocida* in swine, where retreatment is impractical due to husbandry conditions or where repeated retreatment is inadvisable.

Refer to Package Insert for Complete Directions

Dosage: Store at room temperature 15°-30°C (59°-86°F). Keep from freezing.
Resistant Drug (Keflin®)—
Use Only as Directed
Not For Human Use
U.S. Patent No. 4,811,885



Manufactured by
Animal Health
Kenilworth, NJ 07033
© 1987, Pfizer Inc. All rights reserved.

800
79-4982-00-2
Made in USA

4690

Liquamycin®
LA-200®
(oxytetracycline injection)

Antibiotic

Each mL contains 200 mg of
oxytetracycline base as amphoteric
oxytetracycline

For the treatment of disease in beef
cattle, dairy cattle, calves, including
preweaning liveall calves and swine

For animal use only

Net Contents: 100 mL

NADA #113 232, Approved by FDA



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m/ol
ycir

PULL SLOWLY TO OPEN



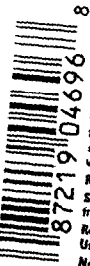
4636

Liquamycin LA-200 (oxytetracycline injection) is a sterile, preconstituted solution of the broad-spectrum antibiotic oxytetracycline. Each mL contains 200 mg of oxytetracycline base as amphoteric oxytetracycline, and on a w/v basis, 40.0% 2-pyrrolidone, 5.0% potassium ethanolate, 0.2% sodium formaldehyde sulfoxylate (as a preservative), 1.8% magnesium oxide, and 0.2% sodium hydrochloric acid as required to adjust pH.

CAUTION: When administered to cattle, muscle discoloration may necessitate trimming of the injection site(s) and surrounding tissues during the dressing procedure.

Warnings: Discontinue treatment at least 28 days prior to slaughter of cattle and swine. Milk taken from animals during treatment and for 96 hours after the last treatment must not be used for food.

Precautions: Exceeding the highest recommended level of drug per lb of body weight per day, administering more than the recommended number of treatments, and/or exceeding 10 mL intramuscularly or subcutaneously per injection site in adult beef and dairy cattle, and 5 mL intramuscularly per injection site in adult swine, may result in antibiotic residues beyond the withdrawal period.



Dosage:

Cattle: A single dosage of 9 mg of oxytetracycline per lb of body weight (4.5 mL/100 lb) administered intramuscularly or subcutaneously is recommended in the treatment of the following conditions: 1) bacterial pneumonia caused by *Pasteurella* spp. (shipping fever) in calves and yearlings, where retreatment is impractical due to husbandry conditions, such as cattle on range, or where repeated restraint is inadvisable, 2) infectious bovine keratoconjunctivitis (pink eye) caused by *Moraxella bovis*.

Swine: A single dose of 9 mg of oxytetracycline per lb of body weight (4.5 mL/100 lb) administered intramuscularly is recommended in the treatment of bacterial pneumonia caused by *Pasteurella multocida* in swine, where retreatment is impractical due to husbandry conditions or where repeated restraint is inadvisable.

Refer to Package Insert for Complete Directions

Storage: Store at room temperature 15°-30°C (59°-86°F). Keep from freezing.

Restricted Drug (California)—
Use Only as Directed
Not For Human Use
U.S. Patent No. 4,018,889

Pfizer
Animal Health
Kalamazoo, MI 49001, U.S.A.
Div. of Pfizer Inc.
NY, NY 10017



Liquamycin[®] LA-200[®] (oxytetracycline injection)

Antibiotic

Each mL contains 200 mg
of oxytetracycline base as
amphoteric oxytetracycline

For the treatment of disease in
beef cattle; dairy cattle; calves,
including preweaning (veal)
calves; and swine

For animal use only

Net Contents: 250 mL

NADA #113-232, Approved by FDA



PULL SLOWLY TO OPEN



Liquamycin LA-200 (oxytetracycline injection) is a sterile, preconstituted solution of the broad-spectrum antibiotic oxytetracycline. Each mL contains 200 mg of oxytetracycline base as amphoteric oxytetracycline, and on a w/v basis, 40.0% 2-pyrrolidone, 5.0% povidone, 1.8% magnesium oxide, 0.2% sodium formaldehyde sulfoxylate (as a preservative), monoethanolamine and/or hydrochloric acid as required to adjust pH.

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Precautions: Exceeding the highest recommended level of drug per lb of body weight per day, administering more than the recommended number of treatments, and/or exceeding 10 mL intramuscularly or subcutaneously per injection site in adult beef and dairy cattle, and 5 mL intramuscularly per injection site in adult swine, may result in antibiotic residues beyond the withdrawal period.

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Refer to Package Insert for Complete Directions

Storage: Store at room temperature 15°–30°C (59°–86°F). Keep from freezing.

**Restricted Drug (California)—
Use Only as Directed**

Not For Human Use
U.S. Patent No. 4,018,889



Animal Health
Kalam, PA 15061, USA
Div. of Pfizer Inc.
NY, NY 10017

986
73-4984-00-1
Made in USA

4637



Liquamycin[®] LA-200[®] (oxytetracycline injection)

Antibiotic

Each mL contains 200 mg
of oxytetracycline base as
amphoteric oxytetracycline

For the treatment of disease in
beef cattle; dairy cattle; calves;
including preruminating (veal)
calves; and swine

For animal use only

Net Contents: 500 mL

NADA #113-232, Approved by FDA



4697

Liquamycin®
LA-200®
(oxytetracycline injection)

Antibiotic

Each mL contains 200 mg
of oxytetracycline base as
amphoteric oxytetracycline.

For the treatment of disease
in beef cattle; dairy cattle; calves,
including preruminating (veal)
calves; and swine

For animal use only

Net Contents: 500 mL

NADA #113-232, Approved by FDA

Liquamycin®
LA-200®
(oxytetracycline injection)



0 87219 04697 5



104984000

986 10-4984-00-0



Liquamycin LA-200 (oxytetracycline injection) is a sterile, preconstituted solution of the broad-spectrum antibiotic oxytetracycline.

Caution: When administered to cattle, muscle discoloration may necessitate trimming of the injection site(s) and surrounding tissues during the dressing procedure.

Warnings: Discontinue treatment at least 28 days prior to slaughter of cattle and swine. Milk taken from animals during treatment and for 96 hours after the last treatment must not be used for food.

Precautions: Exceeding the highest recommended level of drug per lb of body weight per day, administering more than the recommended number of treatments, and/or exceeding 10 mL intramuscularly or subcutaneously per injection site in adult beef and dairy cattle, and 5 mL intramuscularly per injection site in adult swine, may result in antibiotic residues beyond the withdrawal period.

Refer to Package Insert for Complete Directions

Storage: Store at room temperature 15°–30°C (59°–86°F). Keep from freezing.

Restricted Drug (California)—

Use Only as Directed

Not for Human Use

TAKE TIME



OBSERVE LABEL DIRECTIONS



Distributed by:

Animal Health

Exton, PA 19341, USA
Div. of Pfizer Inc
NY, NY 10017

Liquamycin[®] LA-200[®] (oxytetracycline injection)

Cattle Dosage Guide

At the first signs of pneumonia or pinkeye,* administer a single dose of Liquamycin LA-200 by deep intramuscular injection, or subcutaneously, according to the following weight categories.**

Animal Weight (lb)	Number of mL or cc	Animal Weight (lb)	Number of mL or cc
100	4.5	700	31.5
200	9.0	800	36.0
300	13.5	900	40.5
400	18.0	1000	45.0
500	22.5	1100	49.5
600	27.0	1200	54.0

* See package insert for dosing instructions for other indicated diseases and full product information.

** Do not administer more than 10 mL at any one injection site (1–2 mL per site in small calves)

Discontinue treatment at least 28 days prior to slaughter.

Swine Dosage Guide

At the first signs of pneumonia,* administer Liquamycin LA-200 by deep intramuscular injection according to the following weight categories.**

Animal Weight (lb)	Number of mL or cc	Animal Weight (lb)	Number of mL or cc
10	0.5	175	7.9
25	1.1	200	9.0
50	2.3	225	10.1
75	3.4	250	11.3
100	4.5	275	12.4
125	5.6	300	13.5
150	6.8	325	14.6

* See package insert for dosing instructions for other indicated diseases and full product information.

** Do not administer more than 5 mL at any one injection site.

Discontinue treatment at least 28 days prior to slaughter.

U.S. Patent No. 4,018,889

986
10-4984-00-0
Made in USA

EXP. DATE:

LOT NO.:

KEEP FROM FREEZING

STORE AT ROOM TEMPERATURES 15-30°C (59-86°F)

(an allergic reaction) or to cardiovascular collapse of unknown cause.
possibly death. Some of these reactions may be attributed either to anaphylaxis?
respiratory abnormalities (labored breathing, frothing at the mouth, collapse and
swelling of eyelids, ears, muzzle, anus and vulva (or scrotum and sheath in males),
tracheal administration includes injection site swelling, restlessness, ataxia, trembling,
ADVERSE REACTIONS: Reports of adverse reactions associated with oxy-

Refer to package insert for complete indications, dosage, and usage.
is impractical due to husbandry conditions, or where repeated treatment is inadvisable.
of bacterial pneumonia caused by *Pasteurella multocida* in swine, where re-treatment
weight (4.5 mL/100 lb.) administered intramuscularly is recommended in the treatment

CATTLE: A single dosage of 9 milligrams of oxytetracycline per pound of body
weight (4.5 mL/100 lb.) administered intramuscularly or subcutaneously is recom-

ended in the treatment of the following conditions: (1) bacterial pneumonia caused
by *Pasteurella* spp. (shipping fever) in calves and yearlings, where re-treatment is
impractical due to husbandry conditions, such as cattle on the range, or where repeated
treatment is inadvisable, and (2) infectious bovine keratoconjunctivitis (pink eye) caused
by *Moraxella* spp.

SWINE: A single dosage of 9 milligrams of oxytetracycline per pound of body
weight (4.5 mL/100 lb.) administered intramuscularly is recommended in the treatment

DOSEAGE

PENNOX 200

.....OXYTETRACYCLINE INJECTION

Antibiotic

Each mL contains 200 mg of oxytetracycline base as amphoteric oxytetracycline.

For treatment of disease in beef cattle, dairy cattle, calves, including pre-ruminating (veal) calves, and swine.

For Animal Use Only

Net Contents: 500 mL

PennField

ANADA 200-154; Approved by FDA

PENNOX[®] 200 (oxytetracycline injection) is a sterile, preconstituted solution of the broad spectrum antibiotic, oxytetracycline. Each mL contains 200 mg of oxytetracycline base as amphoteric oxytetracycline and on a w/v basis: 40.0% 2-pyrolidone, 5.0% povidone, 1.8% magnesium oxide, 0.2% sodium formaldehyde sulfoxylate (as a preservative), monoethanolamine and/or hydrochloric acid as required to adjust pH.

WARNING: Discontinue treatment at least 28 days prior to the slaughter of cattle or swine. Milk taken from animals during treatment and for 96 hours after the last treatment must not be used for food. Rapid intravenous administration may result in animal collapse. Oxytetracycline should be administered intravenously slowly over a period of at least 5 minutes.

PRECAUTIONS: Exceeding the highest recommended level of drug per pound of body weight per day, administering more than the recommended number of treatments, and/or exceeding 10 mL intramuscularly or subcutaneously per injection site in adult beef cattle and dairy cattle, and 5 mL intramuscularly per injection site in adult swine, may result in antibiotic residues beyond the withdrawal period. Consult with your veterinarian prior to administering this product in order to determine the proper treatment required in the event of an adverse reaction. At the first sign of any adverse reaction, discontinue use of product and seek the advice of your veterinarian. Some of the reactions may be attributed to anaphylaxis (an allergic reaction) or to cardiovascular collapse of unknown cause.

Distributed by:
PennField Animal Health
Omaha, NE 68144
Not for Human Use. Use Only as Directed.
Restricted Drug (California)

PennoxTM 200

***** OXYTETRACYCLINE INJECTION

2

Antibiotic

Each mL contains 200 mg of oxytetracycline base as amphoteric oxytetracycline.
For Use in Beef Cattle, Dairy Cattle, Calves Including Pre-ruminating (Veal) Calves, and Swine.
For Animal Use Only

READ ENTIRE BROCHURE CAREFULLY BEFORE USING THIS PRODUCT.

PENNOXTM 200 (oxytetracycline injection) is a sterile, ready-to-use solution for the administration of the broad-spectrum antibiotic oxytetracycline by injection. Oxytetracycline is an antimicrobial agent that is effective in the treatment of a wide range of diseases caused by susceptible gram-positive and gram-negative bacteria.

PENNOXTM 200 does not require refrigeration; however, it is recommended that it be stored at room temperature, 15°-30°C (59°-86°F).

The antibiotic activity of oxytetracycline is not appreciably diminished in the presence of body fluids, serum, or exudates.

WARNING

Discontinue treatment at least 28 days prior to the slaughter of cattle or swine. Milk taken from animals during treatment and for 96 hours after the last treatment must not be used for food. Rapid intravenous administration may result in animal collapse. Oxytetracycline should be administered intravenously slowly over a period of at least 5 minutes.

ADVERSE REACTIONS

Reports of adverse reactions associated with oxytetracycline administration include injection site swelling, restlessness, ataxia, trembling, swelling of eyelids, ears, muzzle, anus and vulva (or scrotum and sheath in males), respiratory abnormalities (labored breathing), frothing at the mouth, collapse and possibly death. Some of these reactions may be attributed either to anaphylaxis (an allergic reaction) or to cardiovascular collapse of unknown cause.

PRECAUTIONS

Exceeding the highest recommended dosage level of drug per pound of body weight per day, administering more than the recommended number of treatments, and/or exceeding 10 mL intramuscularly or subcutaneously per injection site in adult beef cattle and dairy cattle, and 5 mL intramuscularly per injection site in adult swine, may result in antibiotic residues beyond the withdrawal period.

Consult with your veterinarian prior to administering this product in order to determine the proper treatment required in the event of an adverse reaction. At the first sign of any adverse reaction, discontinue use of product and seek the advice of your veterinarian. Some of the reactions may be attributed either to anaphylaxis (an allergic reaction) or to cardiovascular collapse of unknown cause.

Shock may be observed following intravenous administration, especially where highly concentrated materials are involved. To minimize this occurrence, it is recommended that **PENNOXTM 200** be administered *slowly* by this route.

Shortly after injection, treated animals may have transient hemoglobinuria resulting in darkened urine.

As with all antibiotic preparations, use of this drug may result in overgrowth of nonsusceptible organisms, including fungi. A lack of response by the treated animal, or the development of new signs, may suggest that an overgrowth of nonsusceptible organisms has occurred. If any of these conditions occur, consult your veterinarian.

Since bacteriostatic drugs may interfere with the bactericidal action of penicillin, it is advisable to avoid giving **PENNOXTM 200** in conjunction with penicillin.

STORAGE: Store at room temperature, 15°-30°C (59°-86°F). Keep from freezing.

CARE OF SICK ANIMALS

The use of antibiotics in the management of diseases is based on an accurate diagnosis and an adequate course of treatment. When properly used in the treatment of diseases caused by oxytetracycline-susceptible organisms, most animals that have been treated with **PENNOXTM 200** show a noticeable improvement within 24 to 48 hours. It is recommended that the diagnosis and treatment of animal diseases be carried out by a veterinarian. Since many diseases look alike but require different types of treatment, the use of professional veterinary and laboratory services can reduce treatment time, cost and needless losses. Good housing, sanitation and nutrition are important in the maintenance of healthy animals, and are essential in the treatment of diseased animals.

INDICATIONS

PENNOXTM 200 is intended for the use in the treatment of the following diseases in beef cattle, dairy cattle; calves, including pre-ruminating (veal) calves; and swine when due to oxytetracycline-susceptible organisms.

BEEF CATTLE, DAIRY CATTLE AND CALVES, INCLUDING PRE-RUMINATING (VEAL) CALVES

In cattle, **PENNOXTM 200** is indicated in the treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Hemophilus* spp.; infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*; foot-rot and diphtheria caused by *Fusobacterium necrophorum*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresii*; leptospirosis caused by *Leptospira pomona*; and wound infections and acute metritis caused by strains of staphylococci and streptococci organisms susceptible to oxytetracycline.

SWINE

In swine, **PENNOXTM 200** is indicated in the treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*; pneumonia caused by *Pasteurella multocida*; and leptospirosis caused by *Leptospira pomona*.

In sows, **PENNOXTM 200** is indicated as an aid in the control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli*.

DOSAGE

BEEF CATTLE, DAIRY CATTLE AND CALVES, INCLUDING PRE-RUMINATING (VEAL) CALVES

PENNOXTM 200 is to be administered by intramuscular, subcutaneous or intravenous injection to beef cattle and dairy cattle; and calves, including pre-ruminating (veal) calves.

A single dosage of 9 milligrams of **PENNOXTM 200** per pound of body weight administered intramuscularly or subcutaneously is recommended in the treatment of the following conditions: (1) bacterial pneumonia caused by *Pasteurella* spp. (shipping fever) in calves and yearlings, where re-treatment is impractical due to husbandry conditions, such as cattle on the range, or where their repeated restraint is inadvisable; and (2) infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*.

PENNOXTM 200 can also be administered by intravenous, subcutaneous, or intramuscular injection at a level of 3 to 5 milligrams of oxytetracycline per pound of body weight per day. In the treatment of severe foot-rot and advanced cases of other indicated diseases, a dosage level of 5 milligrams per pound of body weight per day is recommended. Treatment should be continued for 24 to 48 hours following remission of disease signs; however, not to exceed a total of four consecutive days. Consult your veterinarian if improvement is not noted within 24 to 48 hours of the beginning of treatment.

SWINE

In swine, a single dosage of 9 milligrams of **PENNOXTM 200** per pound of body weight administered intramuscularly is recommended in the treatment of bacterial pneumonia caused by *Pasteurella multocida* in swine, where re-treatment is impractical due to husbandry conditions or where repeated restraint is inadvisable. **PENNOXTM 200** can also be administered by intramuscular injection at a level of 3 to 5 milligrams of oxytetracycline per pound of body weight per day. Treatment should be continued 24 to 48 hours following remission of disease signs; however, not to exceed a total of four consecutive days. Consult your veterinarian if improvement is not noted within 24 to 48 hours of the beginning of treatment.

For sows, administer once intramuscularly 3 milligrams of oxytetracycline per pound of body weight approximately 8 hours before farrowing or immediately after completion of farrowing.

For swine weighing 25 lb of body weight and under, PENNOX™ 200 should be administered undiluted for treatment at 9 mg/lb, but should be administered diluted for treatment at 3 or 5 mg/lb.

Body Weight	9 mg/lb Dosage	3 or 5 mg/lb Dosage		
	Volume of UNDILUTED PENNOX™ 200	Volume of DILUTED PENNOX™ 200		
	9 mg/lb	3 mg/lb Dilution* 5 mg/lb		
5 lb	0.2 mL	0.6 mL	1:7	1.0 mL
10 lb	0.5 mL	0.9 mL	1:5	1.5 mL
25 lb	1.1 mL	1.5 mL	1:3	2.5 mL

*To prepare dilutions, add one part PENNOX™ 200 to three, five, or seven parts of sterile water, or 5 percent dextrose solution as indicated; the diluted product should be used immediately.

DIRECTIONS FOR USE

PENNOX™ 200 is intended for use in the treatment of disease due to oxytetracycline-susceptible organisms in beef cattle, dairy cattle, calves including pre-ruminating (veal) calves, and swine. A thoroughly cleaned, sterile needle and syringe should be used for each injection (needles and syringes may be sterilized by boiling in water for 15 minutes). In cold weather, PENNOX™ 200 should be warmed to room temperature before administration to animals. Before withdrawing the solution from the bottle, disinfect the rubber cap on the bottle with a suitable disinfectant, such as 70 percent alcohol. The injection site should be similarly cleaned with the disinfectant. Needles of 16 to 18 gauge and 1-1/2 inches long are adequate for intramuscular injections. Needles 2 to 3 inches are recommended for intravenous use.

SUBCUTANEOUS ADMINISTRATION

Subcutaneous injections in beef cattle, dairy cattle and calves, including pre-ruminating (veal) calves, should be made by directing the needle of suitable gauge and length through the loose folds of the neck skin in front of the shoulder. Care should be taken to ensure that the tip of the needle has penetrated the skin, but is not lodged in muscle. Before injecting the solution, pull back gently on the plunger. If blood appears in the syringe, a blood vessel has been entered; withdraw the needle and select a different site. The solution should be injected slowly into the area between the skin and muscles. No more than 10 mL should be injected subcutaneously at any one site in adult beef cattle and dairy cattle; rotate injection sites for each succeeding treatment. The volume administered per injection site should be reduced according to age and body size so that 1 to 2 mL per site is injected in small calves.

INTRAMUSCULAR ADMINISTRATION

Intramuscular injections should be made by directing the needle of suitable gauge and length into the fleshy part of a thick muscle such as in the rump, hip, or thigh regions, avoid blood vessels and major nerves. Before injecting the solution, pull back gently on the plunger. If blood appears in the syringe, a blood vessel has been entered; withdraw the needle and select a different site. No more than 10 mL should be injected intramuscularly at any one site in adult beef cattle and dairy cattle, and not more than 5 mL per site in adult swine, rotate injection sites for each succeeding treatment. The volume administered per injection site should be reduced according to age and body size so that 1 to 2 mL per site is injected in small calves.

INTRAVENOUS ADMINISTRATION

PENNOX™ 200 (oxytetracycline injection) may be administered intravenously to beef cattle and dairy cattle. As with all highly concentrated materials.

PENNOX™ 200 should be administered slowly by the intravenous route.

Preparation of the Animal for Injection:

1. Approximate the location of a vein. The jugular vein runs in the jugular groove on each side of the neck from the angle of the jaw to just above the basket and slightly above and to the side of the windpipe. (See Fig. 1)
2. Restraint. A stanchion or chute is ideal for restraining the animal. With a halter, rope, or cattle leader (nose tongs), pull the animal's head around the side of the stanchion, cattle chute or post in such a manner to form a bow in the neck (See Fig. 2); then snub the head securely to prevent movement. By forming the bow in the neck, the outside curvature of the bow tends to expose the jugular vein and make it easily accessible. **Caution:** Avoid restraining the animal with a tight rope or halter around

the throat or upper neck which might impede blood flow. Animals that are down present no problem so far as restraint is concerned.

3. Clip hair in the area where the injection is to be made (over the vein in the upper part of the neck). Clean and disinfect the skin with alcohol or other suitable antiseptic.

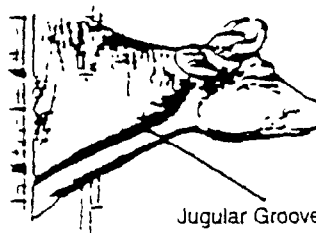


FIGURE 1

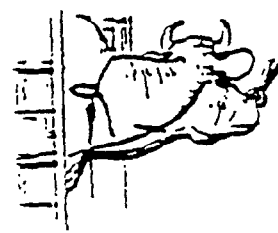


FIGURE 2

Entering the Vein and Making the Injection:

1. Raise the vein. This is accomplished by tying the choke rope tightly around the neck close to the shoulder. The rope should be tied in such a way that it will not come loose and so that it can be untied quickly by pulling the loose end (See Fig. 2). In thick-necked animals, a block of wood placed in the jugular groove between the rope and the hide will help considerably in applying the desired pressure at the right point. The vein is a soft flexible tube through which blood flows back the heart. Under ordinary conditions, it cannot be seen or felt with the fingers. When the flow of blood is blocked at the base of the neck by the choke rope, the vein becomes enlarged and rigid because of the back pressure. If the choke rope is sufficiently tight, the vein stands out and can easily be seen and felt in thin-necked animals. As a further check in identifying the vein, tap it with the fingers in front of the point being tapped will confirm the fact that the vein is properly distended. It is impossible to put the needle in to the vein unless it is distended. Experienced operators are able to raise the vein simply by hand pressure, but the use of a choke rope is more certain.
2. Inserting the needle. This involves three distinct steps. First, insert the needle through the hide. Second, insert the needle into the vein. This may require two or three attempts before the vein is entered. The vein has a tendency to roll away from the point of the needle, especially if the needle is not sharp. The vein can be steadied by the finger and thumb of one hand. With the other hand, the needle point is placed directly over the vein, slanting it so its direction is along the length of the vein, either toward the head or heart. Properly positioned this way, a quick thrust of the needle will be followed by a spurt of blood through the needle, which indicates the vein has been entered. Third, once in the vein, the needle should be inserted along the length of the vein all the way to the hub, exercising caution to see that the needle does not penetrate the opposite side of the vein. Continuously steady flow of blood through the needle indicates that the needle is still in the vein. If blood does not flow continuously, the needle is out of the vein (or clogged) and another attempt must be made. If difficulty is encountered, it may be advisable to use the vein on the other side of the neck.
3. While the needle is being placed in proper position in the vein, an assistant should get the medication ready so that injection can be started without delay after the vein has been entered.
4. Making the injection. With the needle in position as indicated by the continuous flow of blood, release the choke rope by a quick pull on the free end. This is essential, the medication cannot flow into the vein while it is blocked. Immediately connect the syringe containing PENNOX™ 200 (oxytetracycline injection) to the needle and slowly depress the plunger. If there is resistance to depression of the plunger, this indicates the needle has slipped out of the vein (or is clogged) and the procedure will have to be repeated. Watch for any swelling under the skin near the needle, which would indicate that the medication is not going into the vein. Should this occur, it is best to try the vein on the opposite side of the neck.
5. Removing the needle. When injection is complete, remove needle with a straight pull. Then apply pressure over the area of the injection momentarily to control any bleeding through needle puncture, using cotton soaked in alcohol or other suitable antiseptic.

LIVESTOCK DRUG. NOT FOR HUMAN USE. RESTRICTED DRUG (CALIFORNIA). USE ONLY AS DIRECTED.

ANADA 200-154: Approved by FDA

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ANIMAL HEALTH™